**PROFOUND MEDICAL CORP.**

# MANAGEMENT'S DISCUSSION AND ANALYSIS

**MARCH 31, 2022**

**PRESENTED IN US DOLLARS (000s)**

The following Management's Discussion and Analysis ("**MD&A**") prepared as of May 9, 2022, should be read in conjunction with the March 31, 2022 unaudited interim condensed consolidated financial statements and related notes of Profound Medical Corp. ("**Profound**" or the "**Company**"). The unaudited interim condensed consolidated financial statements of Profound and related notes were prepared in accordance with International Financial Reporting Standards ("**IFRS**") as issued by the International Accounting Standards Board applicable to the preparation of interim financial statements, including International Accounting Standard 34, Interim Financial Reporting. Unless stated otherwise, all references to "$" are to United States dollars and all references to "C$" are to Canadian dollars. In this MD&A, unless the context requires otherwise, references to "Profound", "the Company", "we", "us" or "our" are references to Profound Medical Corp. and its subsidiaries.

## FORWARD-LOOKING STATEMENTS

This MD&A contains "forward-looking statements" within the meaning of Section 27A of the US Securities Act and Section 21E of the Exchange Act pursuant to the "safe harbor" provisions of the United States Private Securities Litigation Reform Act of 1995, and "forward-looking information" within the meaning of applicable Canadian securities laws, which include all statements other than statements of historical fact contained in this MD&A, such as statements that relate to the Company's current expectations and views of future events. Often, but not always, forward-looking statements can be identified by the use of words such as "may", "will", "expect", "anticipate", "predict", "aim", "estimate", "intend", "plan", "seek", "believe", "potential", "continue", "is/are likely to", "is/are projected to" or the negative of these terms, or other similar expressions intended to identify forward-looking statements. These forward-looking statements include, among other things, statements relating to:

- our expectations regarding commercializing our approved products (particularly the TULSA-PRO® system following US Food and Drug Administration ("**FDA**") clearance) and our ability to generate revenues and achieve profitability;
- our expectations regarding the safety, efficacy and advantages of our products over our competitors and alternative treatment options;
- our expectations regarding our products fulfilling unmet clinical needs and achieving market acceptance among patients, physicians and clinicians;
- our expectations regarding reimbursement for our approved products from third-party payors;
- our expectations regarding an out-of-pocket market for the Company's products;
- our expectations regarding our relationships with Koninklijke Philips N.V. ("**Phillips**"), Siemens Healthcare GmBH ("**Siemens**") and GE Healthcare ("**GE**"), and our ability to achieve compatibility of our systems with magnetic resonance imaging ("**MRI**") scanners produced by other manufacturers;
- our expectations regarding our ability to expand the installation of TULSA-PRO® systems in Akumin Centres outside of the State of Florida pursuant to our multi-site imaging agreement (the "**Akumin Agreement**") with Akumin Inc. ("**Akumin**");
- our ability to attract, develop and maintain relationships with other suppliers, manufacturers, distributors and strategic partners;
- our expectations regarding our pipeline of product development, including expanding the clinical application of our products to cover additional indications;
- our expectations regarding current and future clinical trials, including the timing, enrollment and results thereof;
- our expectations regarding maintenance of the current regulatory approvals we have received, including our compliance with the conditions under such approvals, and the receipt of additional regulatory approvals for our products and future product candidates;
- our mission and future growth plans;
- our ability to attract and retain personnel;
- our expectations regarding our competitive position for each of our products in the jurisdictions where they are approved;
- our expectations regarding the impact of COVID-19 on the Company's business, affairs, operations, financial condition, liquidity, availability of credit and results of operations;
- our ability to raise debt and equity capital to fund future product development, pursue regulatory approvals and commercialize our approved products;
- our remediation plan with respect to our internal controls over financial reporting; and
- anticipated trends and challenges in our business and the markets in which we operate.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Profound to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those factors discussed in the section entitled "Risk Factors" in the Company's Annual Information Form prepared as of March 3, 2022, for the year ended December 31, 2021 (the "**AIF**"), available on SEDAR at www.sedar.com and filed as an exhibits to the Company's annual report on Form 40-F, filed on March 3, 2022 (the "**40-F**"), available on EDGAR at www.sec.gov, such as:

- risks related to our limited operating history and history of net losses;
- risks related to our liquidity and financing needs;

- risks related to our ability to commercialize our approved products, including realizing the anticipated benefits of our commercial agreement with RadNet Inc. ("**RadNet**"), the Akumin Agreement and our co-development agreement with GE (the "**GE Agreement**"), expanding our sales and marketing capabilities, increasing our manufacturing and distribution capacity, increasing reimbursement coverage for our approved products and achieving and maintaining market acceptance for our products;
- risks related to the regulation of our products, including in connection with obtaining regulatory approvals as well as post-marketing regulation;
- risks related to our successful completion of clinical trials with respect to our products and future product candidates;
- risks related to managing growth, including in respect of obtaining additional funding and establishing and maintaining collaborative partnerships, to achieve our goals;
- risks related to competition that may impact market acceptance of our products and limit our growth;
- risks relating to fluctuating input prices and currency exchange rates;
- risks related to the reimbursement models in relevant jurisdictions that may not be advantageous;
- risks related to reliance on third parties, including our collaborative partners, manufacturers, distributors and suppliers, and increasing the compatibility of our systems with MRI scanners;
- risks related to intellectual property, including license rights that are key to our business;
- risks related to product liability;
- the extent and impact of COVID-19 and the related response from the Company, government (federal, provincial, municipal and state) and regulatory authorities; and
- risks related to the loss of key personnel.

Forward-looking statements contained herein are made as of the date of this MD&A and Profound disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or results or otherwise, unless required by applicable laws. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements due to the inherent uncertainty in them. Readers are cautioned that while Profound believes it has accurately summarized all clinical studies cited in this MD&A, readers should review the full publications of the studies prior to making an investment decision in the Company.

**COVID-19**

The global economy has significantly changed since the beginning of the COVID-19 pandemic. The spread of the COVID-19 virus, declared on March 11, 2020, as a pandemic by the World Health Organization (WHO), has led many governments to adopt exceptional measures to slow the advancement of COVID-19, which measures continue to be significant in Asia. These events cause significant uncertainties and material disruptions to businesses globally, resulting in an economic slowdown that could damage the Company's activities. At the current time, it is not possible to reliably estimate the duration and impact of these events may have on the Company's future financial results because of the uncertainties about future developments. Thus far, the Company has experienced volatility in demand for systems and one-time-use devices, which has resulted in a reduction in anticipated sales and Profound's ability to collect certain payments, particularly in Asia. For more information on COVID-19 and its impact on Profound's business, please refer to the section "Business Update and Sales Strategy".

## BUSINESS OVERVIEW

Profound (NASDAQ: PROF; TSX: PRN) is a commercial-stage medical device company focused on the development and marketing of customizable, incision-free therapeutic systems for the image guided ablation of diseased tissue utilizing its platform technologies and leveraging the healthcare system's existing imaging infrastructure. Profound's lead product (the "**TULSA-PRO® system**") combines real-time MRI, robotically driven transurethral sweeping-action thermal ultrasound with closed-loop temperature feedback control for the ablation of prostate tissue. The product is comprised of one-time-use devices and durable equipment that are used in conjunction with a customer's existing MRI scanner.

In August 2019, the TULSA-PRO® system received FDA clearance as a Class II device in the United States of America ("**United States**" or "**US**") for thermal ablation of prescribed prostate tissue, using transurethral ultrasound ablation ("**TULSA®**") based on the Company sponsored ("**TACT**") whole gland ablation pivotal clinical study. It is also CE marked in the European Union ("**EU**") for ablation of targeted prostate tissue (benign or malignant). The TULSA-PRO® system was approved by Health Canada in November 2019.

Profound believes that, based on the Company's TACT clinical data and additional studies conducted in the EU, physicians may elect to use TULSA-PRO® to ablate benign or malignant prostate tissue in patients with a variety of prostate diseases. Prostate diseases include prostate cancer and benign prostatic hyperplasia ("**BPH**"). Prostate cancer is one of the most common types of cancer affecting men. The annual incidence of newly diagnosed cases in 2022 is estimated to reach 268,490 in the United States according to the American

Cancer Society and in 2020 there were approximately 475,000 newly diagnosed cases of prostate cancer in Europe, according to the International Agency for Research on Cancer. The American Cancer Society further estimates that there are currently 5.8 million men living with prostate cancer in these two geographic regions. Although ten-year survival outcomes for prostate cancer remain favorable, it is still one of most common causes of cancer deaths among men. BPH is a histologic diagnosis that refers to the proliferation of smooth muscle and epithelial cells within the prostatic transition zone. According to the American Urological Association, BPH is nearly ubiquitous in the aging male population with worldwide autopsy proven histological prevalence increases starting at ages 40 to 45 years, reaching 60% at age 60 and 80% at age 80.

Profound initiated the commercial launch of its lead product, the TULSA-PRO® system in the United States in Q4 2019, treating the first patient in a non-trial setting in January 2020. In addition, Profound continues to support additional clinical trials in the United States and abroad to further increase the body of clinical evidence that may be needed particularly for reimbursement and coverage of its technologies by private and government healthcare providers. The Company continues to expand the compatibility of its TULSA-PRO® system with additional MRI brands to broaden its ability to utilize the global MRI installed base and seek regulatory approvals of its products in additional international jurisdictions.

Profound's second product, the Sonalleve® system, is CE marked in the EU for the treatment of uterine fibroids and palliative pain relief associated with metastases in bone and has also been approved by the National Medical Products Association, the regulatory body in China, for non-invasive treatment of uterine fibroids. In late 2020, Sonalleve® received Humanitarian Device Exemption (HDE) approval from the FDA for the treatment of Osteoid Osteoma in the United States. The Sonalleve® system is only compatible with certain Philips MRI's.

Profound deploys a recurring revenue business model in the United States to market TULSA-PRO®, charging a one-time bundled payment per patient that includes the supply of its one-time-use devices, use of the system, as well as the Company's customer and technological support ("**Genius**") services that support each TULSA center with clinical and patient recruitment. The Sonalleve® product is marketed primarily outside North America in European and Asian countries, deploying a capital sales model. Outside of North America, Profound generates most of its revenues from its system sales in Europe and Asia, where the Company deploys a more traditional hybrid business model, charging for the system separately as a capital sale and an additional per patient charge for the one-time-use devices and associated Genius services.

**Profound's Technology**

TULSA-PRO® and Sonalleve® share the common technological concept of using MRI to enable visualization by the surgeon of desired tissue in real time. Both products also use thermal ultrasound technology to gently heat and ablate tissue using the real-time thermometry capability of the MRI.

TULSA-PRO® delivers its ultrasound energy through a transurethral catheter, a one-time-use device that is placed in the patient's prostate through a natural orifice. Focused ultrasound energy is then delivered by the catheter in the shape of a blade. Externally the catheter is connected to a software controlled robotic manipulator that rotates up to 360-degree in a sweeping action to impart thermal energy and thus ablation of tissue. The real time temperature measurement of the prostate is coupled with closed loop process control that meters the appropriate amount of ultrasound energy to gently heat the physician-prescribed region of prostate tissue to the target temperature to achieve cell kill without boiling or charring the tissue. As a measure to keep the urethra within the prostate viable, the temperature of the transurethral catheter is maintained at an appropriate level by circulating water inside the catheter. Similarly, a water-cooled specially designed catheter is placed in the patient's rectum during the ablation process to keep it protected from thermal damage during the procedure. Profound believes that TULSA-PRO®'s controlled and relatively gentle heating process may result in lower post procedural pain, reduced potential of life affecting side effects and in significantly desirable shrinkage of the prostate via resorption of the dead tissue over time, which may provide a longer-term durable benefit.

Sonalleve® delivers its ultrasound energy via a disc located outside the patient. Its ultrasound energy is focused to create small cylindrical hot spots a certain distance into the patient. Overlapping cylinders create ablation of the physician-prescribed desired tissue. Similar to TULSA-PRO, Sonalleve® also provides for controlled temperature increases to achieve cell kill.

The physician is in charge of using the Profound devices and decides which tissue needs to be ablated to impart therapeutic effect. Profound believes that in the hands of trained physicians, its systems have the ability to provide customizable, incision-free ablative therapies with the precision of real-time MRI visualization and thermometry, focused ultrasound and closed-loop temperature feedback control. Profound believes that its technology offers clinicians and appropriate patients a better alternative to traditional surgical or radiation therapies, with respect to clinical outcomes, side effects and recovery time.

**TULSA-PRO®**

The TULSA-PRO® system is designed to provide customizable and predictable ablation of a surgeon defined region of prostate while actively protecting the urethra and rectum to help preserve the patient's natural functional abilities. To date, over 2,000 global TULSA-PRO® procedures have been performed by more than 100 physicians at over 30 commercial and 20 clinical research sites.

Clinical Studies

In March 2014, Profound completed enrollment and treatment of 30 patients in the Phase I TULSA multi-jurisdictional safety and precision study. Based on the Phase I clinical trial results, in April 2016, Profound received a CE Certificate of Conformity for the TULSA-PRO® system from our notified body in the EU, and in the fourth quarter of 2016, Profound initiated a pilot commercial launch of TULSA-PRO® in key European markets where the CE mark is accepted.

Profound received FDA clearance for the TULSA-PRO® system in August 2019 for transurethral ultrasound ablation of prostate tissue, based on the Company's TACT Pivotal Clinical Trial. The TACT Pivotal Clinical Trial is a prospective, open-label, single-arm pivotal clinical study, of 115 treatment-naïve localized prostate cancer patients across 13 research sites in the United States, Canada and Europe, which enrolled patients between August 2016 and February 2018.

Localized Prostate Cancer, Ablation Safety and Efficacy: TACT Pivotal Study

The TACT Pivotal Clinical Trial demonstrates that MRI-guided TULSA is a minimally invasive procedure for effective prostate cancer ablation with a favorable side effect profile, minimal impact on quality of life and low rates of residual disease[1]. In the large, multi-center prospective study in men with predominately intermediate-risk prostate cancer, whole gland ablation sparing the urethra and apical sphincter with the TULSA-PRO® met its primary regulatory endpoint of prostate-specific antigen ("**PSA**") reduction in 96% of men to a median nadir of 0.34 ng/ml and 0.5 ng/ml at 12 months. Median decrease in perfused prostate volume as assessed by a central radiologist using 12-month MRI was 91%, from a median 37 cc to 2.8 cc. At 12 months, extensive biopsy sampling of the markedly reduced prostate volume demonstrated a benefit for nearly 80% of men. There was no evidence of cancer in 65% of men and 14% had low-volume clinically-insignificant disease. The authors, however, noted that thermally-fixed non-viable cells can retain their apparently-malignant tissue morphology, confounding Gleason grading and potentially introducing false positives[2]. By two years, 7% of men sought additional treatment for their prostate cancer (prostatectomy, radiation). The study patient population, with two-thirds of those with Gleason Grade Group (GGG) ≥ 2 having either bilateral disease or at least five positive cores, allowed for evaluation of oncologically relevant secondary outcomes including PSA stability, post-treatment biopsy, and salvage treatment. Notwithstanding the limitations of comparisons between ablative and extirpative therapies, the 7% rate of salvage treatment and 20% rate of residual clinically significant prostate cancer in intermediate-risk patients are in line with accepted rates of early failure or additional intervention after standard treatments and goals for retreatment after ablative therapies.

TULSA was associated with a high degree of safety and maintenance of quality-of-life, comparing favorably to radical prostatectomy and other whole-gland ablation techniques. At 12 months, 96% of men returned to baseline urinary continence, and 75% of potent men maintained or returned to erections sufficient for penetration. A total of 12 grade 3 adverse events occurred in 8% of men, including genitourinary infection (4%), urethral stricture (2%), urinary retention (1.7%), urethral calculus and pain (1%), and urinoma (1%), all resolved by 12 months. There were no grade 4 events, rectal injuries, severe incontinence requiring surgical intervention, or severe erectile dysfunction unresponsive to medication.

Localized Prostate Cancer, Durability of Outcomes: Phase I Safety and Precision Study

The Phase I Clinical Trial demonstrates that MRI-guided TULSA is safe and precise for ablation in patients with localized prostate cancer, providing spatial ablation precision of ± 1.3 mm with a well-tolerated side-effect profile and minor or no impact on urinary, erectile and bowel function at 12 months[3]. There were no grade 4 or higher adverse events, one transient attributable grade 3 event (epididymitis), and notably no injury to rectal or periprostatic structures. Functional outcomes, International Prostate Symptom Score ("**IPSS**") and IIEF-15, both showed a favorable anticipated trend of initial deterioration with subsequent gradual improvement toward baseline levels. Consistent with the conservative whole-gland treatment plan which included a 3 mm circumferential margin expected to spare 10% viable prostate at the gland periphery, intra-operative MRI thermometry measured 90% thermal ablation of the prostate gland, median PSA

[1] Klotz et al, "MRI-guided transurethral ultrasound ablation of prostate cancer," The Journal of Urology, 2020
[2] Anttinen et al, "Histopathological evaluation of prostate specimens after thermal ablation may be confounded by the presence of thermally-fixed cells," International Journal of Hyperthermia, 2019
[3] Chin et al, "Magnetic Resonance Imaging-Guided Transurethral Ultrasound Ablation of Prostate Tissue in Patients with Localized Prostate Cancer: A Prospective Phase 1 Clinical Trial," European Urology, 2016; Bonekamp et al, "Twelve-month prostate volume reduction after MRI-guided transurethral ultrasound ablation of the prostate," European Radiology, 2018

decreased 90% from 5.8 ng/ml to nadir of 0.6 ng/ml, and median prostate volume reduced by 88% on 1-year MRI. Prostate biopsy at one year identified decreased cancer burden with 61% reduction in cancer length; however, attributable to the circumferential safety margin, clinically significant cancer in 9 of 29 men (31%), and any cancer in 16 of 29 (55%).

Follow-up data to three and five years demonstrate durability of the outcomes, with continued treatment safety and stable quality of life, as well as predictable PSA and biopsy oncological outcomes based on treatment-day imaging and early PSA follow-up, without precluding any potential salvage therapy options[4]. Repeat prostate biopsy at three years demonstrated durable histological outcomes, with only one subject upgrading to GGG 1 from negative at 12 months, and one subject upgrading to GGG 2 from GGG 1 at 12 months. Between one and five years, there were no new serious adverse events. By five years, 16 men completed protocol follow-up, three withdrew with PSA <0.4 ng/ml, 10 had salvage therapy without complications (six prostatectomy, three radiation and one laser ablation), and one died of an unrelated cause. Of 16 men with complete follow-up data, five-year median PSA remained at 0.55 ng/ml. Median IPSS of 6 at baseline returned to 5 by three months, and 6.5 at five years. At baseline, 9 of 16 had erections sufficient for penetration, 11 of 16 at one year, and 7 of 16 at five years. All 16 subjects had leak-free, pad-free continence at one and five years. Predictors of salvage therapy included lower ablation coverage and higher PSA nadir. At five years after TULSA, cancer specific survival is 100%, and overall survival 97%.

Benign Prostatic Hyperplasia (BPH), Relief of Lower Urinary Tract Symptoms (LUTS): Phase I Studies

Promising safety and feasibility of the TULSA-PRO® to relieve Lower Urinary Tract Symptoms ("**LUTS**") associated with BPH has been demonstrated in two Phase I studies showing improvements in IPSS comparable to modern minimally invasive surgical therapies[5]. A retrospective analysis of a sub-group of nine men from a localized prostate cancer study who also had LUTS (baseline IPSS ≥ 12) demonstrated significant IPSS improvement of 58% from 16.1 to 6.3 at 12 months (p=0.003), with at least a moderate (≥ 6 points) symptom reduction in eight of nine patients. IPSS Quality of Life ("**QoL**") improved in eight of nine patients. Erectile function (IIEF-EF) remained stable from 14.6 at baseline to 15.7 at 12 months. The proportion of patients with erections sufficient for penetration was unchanged. Full urinary continence (pad-free, leak-free) was achieved at 12 months in all patients. In five men who suffered from more severe symptoms (baseline IPSS ≥ 12 and Qmax < 15 ml/s), peak urine flow rate ("**Qmax**") increased from 11.6 ml/s to 22.5 ml/s at 12 months. All adverse events were mild to moderate with no serious events reported.

A prospective study of TULSA-PRO® for BPH has been conducted with early outcomes presented at the 2020 European Association of Urology Annual Conference. Urinary function improved during the initial three-month follow up among the first seven patients treated, while no adverse effects were seen on sexual and bowel functions: average IPSS decreased from 17.7 to 4.6, IPSS QoL decreased from 4.3 to 1.0, and Qmax increased from 11.5 ml/s to 26.8 ml/s, among several other improved urinary measures. A single adverse event had occurred, abscess of the epididymis requiring drainage at two weeks post therapy.

Radio-recurrent localized prostate cancer, Salvage TULSA (sTULSA): Phase I Study

Salvage ablation of radio-recurrent localized prostate cancer has been evaluated in a prospective study of TULSA-PRO® with early outcomes presented at the 2020 EAU Annual Conference[6]. Ten patients were successfully treated, with a median hospitalization time of 24 hours and catheterization time of four days. Four subjects have completed 12-month follow-up, with average PSA decreased from 4.6 ng/ml to 0.6 ng/ml, and all with no evidence of recurrence on biopsy and imaging (MRI and PSMA-PET). Four patients had prolonged catheterization and subsequent urinary tract infection, and one of these patients had upper urinary tract dilation treated with double-J-stents.

Palliation of symptomatic locally advanced prostate cancer, Palliative TULSA (pTULSA): Phase I Study

Patients with symptomatic locally advanced prostate cancer can suffer from severe urinary retention due to bladder outlet obstruction, intractable hematuria and frequent hospitalization. While these complications are commonly treated by palliative transurethral resection of the prostate ("**TURP**"), the improvement is often insufficient and may exclude patients who cannot discontinue anticoagulants. The safety and feasibility of MRI-guided TULSA was evaluated as an alternative palliative treatment option for men suffering from symptomatic locally advanced prostate cancer[7]. Ten patients with locally advanced prostate cancer were enrolled, half with clinical stage T4 disease and half with clinical T3. Prior to TULSA, all patients had continuous indwelling catheterization due to urinary retention, and 90% had

[4] Nair et al, "MRI-Guided Transurethral Ultrasound Ablation in Patients with Localized Prostate Cancer: Three Year Outcomes of a Prospective Phase I Study", BJU International, 2020; Nair et al, "PD17-03 Five-Year Outcomes from a Prospective Phase I Study of MRI-Guided Transurethral Ultrasound Ablation in Men with Localized Prostate Cancer", AUA 2020 Virtual Experience, Abstract in The Journal of Urology, 2020

[5] Elterman et al, "Relief of Lower Urinary Tract Symptoms after MRI-Guided Transurethral Ultrasound Ablation (TULSA) for localized prostate cancer: Subgroup Analyses in Patients with concurrent cancer and Benign Prostatic Hyperplasia," Journal of Endourology, 2020; Anttinen et al, "Transurethral ultrasound therapy for benign prostatic obstruction in humans," EAU 2020 Conference Presentation

[6] Anttinen et al, "Early experience of salvage MRI-guided transurethral ultrasound ablation (TULSA) for local prostate cancer recurrence after radiotherapy," EAU 2020 Conference Presentation

[7] Anttinen et al, "Palliative MRI-guided transurethral ultrasound ablation for symptomatic locally advanced prostate cancer," Scandinavian Journal of Urology, 2020

history of recurrent and/or ongoing gross hematuria. Three patients had palliative TURP performed six months prior to receiving palliative TULSA, all of which were unsuccessful. One week after palliative TULSA, 50% of men were catheter-free. At last follow-up, 100% of men were free of gross hematuria, and 80% had an improvement in catheterization, with 70% completely catheter-free. Notably, the average hospitalization time from local complications reduced from 7.3 to 1.4 days in the six-month period before and after palliative TULSA. All adverse events were related to urinary tract infections, with two patients requiring intravenous administration of antibiotics and three patients resolved with oral antibiotics alone. No other treatment related adverse events were recorded, with no rectal injury or fistula. Further, there was no need for blood transfusions and there was no perioperative mortality.

CAPTAIN Trial

CAPTAIN (A Comparison of TULSA Procedure vs. Radical Prostatectomy in Participants with Localized Prostate Cancer) is a prospective, multi-centre randomized controlled trial of 201 patients aimed at comparing the safety and efficacy of the TULSA procedure (performed with the TULSA-PRO® system) with radical prostatectomy ("RP") in men with organ-confined, intermediate-risk, Gleason Score 7 (Grade Group 2 and 3) prostate cancer. In the CAPTAIN trial, 134 patients will be randomized to receive one or two TULSA procedures and 67 patients will be randomized to receive RP. The trial is expected to take place at eight or more sites in the United States and two in Canada. Of those, six sites have been activated to date and are currently recruiting patients.

RP is currently the gold-standard surgical treatment for intermediate-risk prostate cancer. RP effectively controls disease but carries risk of significant side effects such as long-term erectile dysfunction and urinary incontinence. The TULSA procedure combines transurethral, robotically-driven therapeutic ultrasound with real-time visualization of temperature and automated control of heating from magnetic resonance thermometry. The high spatial, thermal, and anatomic resolution of the target volume enables precise ablation of prostate tissue while sparing functionally important structures, potentially reducing the risk of side effects relative to RP.

The goal of the CAPTAIN trial is to demonstrate that the efficacy of the TULSA procedure is not inferior to RP, while demonstrating superior quality of life outcomes in patients receiving the TULSA procedure as compared to those patients receiving RP. The primary safety endpoint is the proportion of patients who preserve both erectile potency and urinary continence at one year after treatment. The primary efficacy endpoint is the proportion of patients who are free from any additional treatment for prostate cancer by three years after treatment. Secondary endpoints include comparison of rates of complications, cost effectiveness, and timing of the return to baseline activity. Long-term follow-up will be gathered for up to 10 years after treatment.

**Sonalleve®**

Profound's Sonalleve® system combines real-time MRI and thermometry with focused ultrasound delivered from the outside of the patient to enable customized incision-free ablation of diseased tissue. Profound acquired the Sonalleve® technology from Philips in 2017.

The Sonalleve® system is CE marked in the EU for the treatment of uterine fibroids and palliative pain treatment of bone metastases. The uterine fibroids application is also available for sale in Canada. In 2018, the Sonalleve® system was also approved in China by the National Medical Products Administration for the non-invasive treatment of uterine fibroids. Philips Oy registered Sonalleve® in several Middle East, North African, and South Asian countries. In 2020, Sonalleve® also received HDE from the US FDA for treatment of Osteoid Osteoma.

*Sonalleve® Clinical Applications*

Uterine Fibroids and Adenomyosis

Uterine fibroids are the most common non-cancerous tumors in women of childbearing age. Both surgical and medical treatments are available, and the choice depends on number, size, and location of uterine fibroids, patient's age and preferences, and pregnancy expectations. To date, symptomatic uterine fibroids have been mostly treated with radical surgery (hysterectomy) in women who have completed childbearing, or conservative surgery (myomectomy and endometrial ablation) in women who wish to preserve fertility. Today, the radiologist also has interventional options available. Minimally or non-invasive interventional radiology procedures include uterine artery embolization.

There is currently no ideal treatment for adenomyosis, and new options are needed. Drawing on experience of treatment of uterine fibroids, MR-High Intensity Focused Ultrasound ("**MR-HIFU**") has been explored as a potential new conservative treatment and MR-HIFU is an early-stage, non-invasive, therapeutic technology with the potential to improve the QoL and decrease the cost of care for patients with adenomyosis.

To achieve its current regulatory clearances, the Sonalleve® MR-HIFU System has undergone several studies and clinical trials for uterine applications at Sunnybrook Health Sciences Center (Toronto, Ontario), University Medical Center Utrecht (Utrecht, the Netherlands), University Hospital St. André (Bordeaux, France), Samsung Medical Center (Seoul, Korea), Peking University First Hospital Beijing (Beijing, China), First Affiliated Hospital of Medical College of Xi'an Jiaotong University (Xi'an, China), Turku University Hospital (Turku, Finland), National Institutes of Health (Bethesda, MD, USA), St. Luke's Episcopal Hospital (Houston, TX, USA), amongst others.

In addition, a comprehensive literature review provides supportive evidence showcasing the beneficial action of MR-HIFU in uterine fibroid and adenomyosis therapy. These studies include the Verpalen et al. 2020, Nguyen 2020, Yeo et al. 2017, Kim et al. 2017, and Hocquelet et al. 2017 that utilized the Sonalleve® MR-HIFU System. Specifically, the studies show impressive performance in terms of ablation efficiency, therapeutic efficacy, symptom reduction, and/or QoL improvement. There were no treatment-related serious adverse events in any of these studies, although Browne et al. 2020 describes a procedure-related major complication in the form of deep vein thrombosis that was noted in one patient (0.8%) and subsequently and successfully treated with anticoagulation therapy. Minor adverse events, when present, typically include 1st and 2nd degree skin burns, local swelling, cramps, leg pain, abdominal pain, buttock pain, and back pain, which are all known and anticipated adverse events of MR-HIFU therapy.

Palliative Bone Pain Treatment

Pain caused by bone metastases is common in the event of malignancy and is inevitably associated with serious complications that may deteriorate the QoL of patients and become life threatening.

For patients with bone metastases, clinical evaluation reports were completed in October 2020, showing significant decrease in pain score, dosage of medication, or QoL are to be expected with MR-HIFU bone therapy. The randomized controlled Phase III study by Hurwitz et al. represents some of the most important clinical data that has been reported. In 112 subjects receiving MR-HIFU compared against 35 subjects receiving sham treatment, significant pain reduction at three months (decrease in worst NRS pain ≥ 2 without increase in pain medication) was 64.3% vs. 20.0% ($p<0.001$), with mean Numeric Pain Scale ("**NRS**") reduction of 3.6 ± 3.1 vs. 0.7 ± 2.4 from an initial median NRS score of 7.0 in both groups. Improvement in average Brief Pain Inventory-Quality of Life at three months was 2.4 points superior in the MR-HIFU group ($p<0.001$), representing a clinically important reduction in impairment caused by bone metastasis pain.

The clinical data above shows that patients with bone metastases can expect a statistically significant decrease in pain scores and/or in medication dosage and increase in quality of life with MR-HIFU bone metastasis therapy.

Osteoid Osteoma Treatment

Osteoid osteoma is a relatively rare, painful bone tumor that typically occurs in the cortex of long bones, especially in children and adolescents, and accounts for approximately 10% of all benign bone tumors.

Current osteoid osteoma treatment options include surgery and radiofrequency ablation ("**RFA**"), which is a less invasive option than surgical resection. Although RFA can have a high success rate, the treatment is invasive and can potentially cause minor and major complications. It also exposes patients and operators to ionizing radiation associated with the CT imaging guidance.

Sonalleve® MR-HIFU provides an optimal therapy choice for osteoid osteoma which is a precise, completely non-invasive, and free from ionizing radiation treatment. The recent studies have assessed the use of Sonalleve® MR-HIFU in treatment of osteoid osteoma, showing a high clinical success rate and complete symptom resolution without any serious adverse effects and only few minor adverse effects that promptly resolve. The Sonalleve® MR-HIFU device offers a novel, minimally invasive, MRI-guided method to treat osteoid osteoma safely and effectively.

**Business Update and Sales Strategy**

COVID-19 is altering our business through impacts in healthcare facilities' ability to make commitments and patients deciding to undergo procedures. The global response to the COVID-19 pandemic has resulted in, among other things, border closures, severe travel restrictions, the temporary shut-down of non-essential services and extreme fluctuations in financial and commodity markets. Although these restrictions have eased in the United States, Canada and elsewhere, such measures continue to be implemented by one or more governments in jurisdictions where the Company operates, particularly in Asia. These measures have caused material disruption to businesses globally, including for Profound which has significant operations in Asia. The extent to which COVID-19 and any other pandemic or public health crisis impacts the Company's business, affairs, operations, financial condition, liquidity, availability of credit and results of operations will depend on future developments that are highly uncertain and cannot be predicted with any meaningful precision, including new information which may emerge concerning the severity of the COVID-19 virus and the actions in the countries where we operate that are required to contain the COVID-19 virus or remedy its impact, among others.

Further, from an operational perspective, the Company's employees, direct sales and marketing teams and distribution partners, as well as the workforce of vendors, services providers and counterparties with which the Company does business, may also be adversely affected by the COVID-19 pandemic or efforts to mitigate the pandemic, including government-mandated shutdowns, requests or orders for employees to work remotely, and other physical distancing measures, which could result in an adverse impact on the Company's ability to conduct its businesses, particularly in Asia, including its ability to cultivate adoption of the TULSA-PRO® technology, support clinical customers with TULSA-PRO® procedures and increase the utilization of the systems and one-time use devices.

To date, the economic downturn and uncertainty caused by the COVID-19 pandemic and global measures undertaken to contain its spread have affected all of the Company's operations to some extent and, in particular, have caused volatility in demand for TULSA-PRO® systems and the one-time-use devices related thereto. Profound continues to experience the effects of these measures as they continue to be significant in Asia. This has resulted in a reduction in anticipated sales and led to delays in the Company's expectations regarding the rate at which agreements for new TULSA-PRO® user sites will be entered into and when user sites will become operational for the initiation of patient treatments. Despite the COVID-19 pandemic, patient treatments are continuing, and Profound continues to identify potential new TULSA-PRO® user sites. The Company continues to evaluate the current and potential impact of the COVID-19 pandemic on its business, affairs, operations, financial condition, liquidity, availability of credit and results of operations.

In addition, the actual and threatened spread of COVID-19 globally could also have a material adverse effect on the regional economies in which Profound operates, could continue to negatively impact stock markets, including the trading price of the common shares in the capital of the Company ("**Common Shares**"), could adversely impact the Company's ability to raise capital and could cause continued interest rate volatility and movements that may make obtaining financing more challenging or more expensive.

During the three months ended March 31, 2022, the Company experienced the following key impacts related to COVID-19:

- a reduction in revenue, caused by volatility in demand for systems and one-time-use devices.
- customer payments delayed due to Profound's inability to install systems because of hospital restrictions, and
- a lower than anticipated number of TULSA-PRO procedures performed and related revenue being recognized.

While the adverse impacts of COVID-19 regulations on the Company have lessened in both Canada and the US alongside the loosening of restrictions, the Company has still seen a negative financial impact from COVID-19 during the three months ended March 31, 2022 due to lockdowns and hospital restrictions in Asia. The lockdowns and restrictions have impacted Profound's ability to collect certain payments in these countries, which have impeded our efforts to install our systems and has delayed our collections. Profound continues to work with local authorities and team members located within these countries to help expedite the process. The COVID-19 pandemic remains uncertain in terms of its magnitude, outcome and duration, as well as further social distancing restrictions. Despite the challenging and uncertain economic environment created by the ongoing impact of the COVID-19 pandemic, our business continues to operate normally, and we believe our business demonstrates resilience because of our preparation and strong relationships. Through the implementation of our detailed business continuity plan, we transitioned a significant portion of the Company's employee base to work from home. Throughout these challenging circumstances, the Company has continued to serve its customers, quickly adapting to the current environment.

Profound initiated its launch of the TULSA-PRO® system in the United States in Q4 2019 and the first patient was treated in the United States in a non-clinical trial setting in January 2020. Since then, Profound's business model has evolved to a pay per patient treated model that bundles durable hardware usage, one-time-use devices and Profound's Genius services, which includes necessary clinical support for a productive start-up of the practice.

Profound has generated revenues from capital sales, one-time-use devices and related services, in the EU (principally in Germany) and Asia. For the three months ended March 31, 2022, approximately 45%, 34% and 21% of revenues were generated in the United States, Asia and EU, respectively, compared to approximately 34%, 66% and nil% of revenues which were generated in the United States, EU and Asia, respectively for the three months ended March 31, 2021. Revenue on a quarter over quarter basis is expected to fluctuate given the Company maintaining a limited European commercial effort and remains primarily focused on the US market.

On January 10, 2020, Profound announced the signing of its first-ever US multi-site imaging center agreement for TULSA-PRO® with RadNet, an owner and operator of outpatient imaging centers, pursuant to which Profound will install TULSA-PRO® systems at three RadNet imaging centers in the greater Los Angeles area. To date, one site is currently treating patients, while the installation of the remaining systems and initiation of patient treatments have been delayed as a result of the COVID-19 pandemic.

Profound's TULSA-PRO system is primarily marketed to early adopter physicians who specialize in treatment of prostate disease including urologists and radiologists at opinion leading hospitals. TULSA-PRO services are available at either independent imaging centers or at hospital-based imaging centers.

Historically, treatment of conditions such as localized prostate disease and uterine fibroids have included surgical intervention. Over time, surgery has evolved from an 'open' technique, to laparoscopic, to robotic surgery. The motivation of surgeons behind this evolution has been to perform procedures that reduce invasiveness, improve clinical outcomes and reduce recovery times. Profound is now taking this concept to the next level by enabling customizable, incision-free therapies for the MRI-guided ablation of diseased tissue with the TULSA-PRO® and Sonalleve® systems. These incision-free and radiation-free procedures offer surgeons the option of providing predictable and customizable procedures that eliminate invasiveness, offer the potential to improve clinical outcomes and further reduce hospital stays and patient recovery times.

Profound is establishing its own direct sales and marketing teams for sales of TULSA-PRO® systems and the one-time-use devices related thereto, as well as for Sonalleve® systems in the jurisdictions where it is approved. The primary focus of Profound's direct sales team is to cultivate adoption of the TULSA-PRO® technology, support clinical customers with the TULSA-PRO® procedures and increase the utilization of the systems and one-time-use devices. Profound expects to generate recurring revenues from the use of the system, one-time-use devices, clinical support and service maintenance.

Profound also collaborates with its strategic partners Philips and Siemens for lead generation and distribution of durable equipment, which are currently available through the Philips and Siemens sales catalogs.

Under the agreement with Siemens (the "**Siemens Agreement**"), there is a one-time fixed license fee and per annum payments calculated based on annual volume of Profound's systems that are interfaced to a Siemens MRI scanner. The initial term of the Siemens Agreement is five years and will be automatically extended for successive one-year terms thereafter unless terminated earlier. The Company also obtained a non-exclusive license to Siemens Access I interface software and reasonable support for the term of the Siemens Agreement.

On December 21, 2020, Profound signed the GE Agreement to expand provider access to TULSA-PRO®. Pursuant to the terms of the GE Agreement, Profound will be supplied with additional information to utilize the ExSI interface, which will allow Profound to interface with GE MRI scanners and GE will help support the development efforts of Profound to achieve compatibility with its GE MRI scanners.

On May 6, 2021, Profound signed the Akumin Agreement. Pursuant to the Akumin Agreement, Profound expects to install TULSA-PRO® systems at up to 10 Akumin centers to be outfitted with diagnostic and therapeutic imaging services specifically dedicated towards men's health. The initial geographic focus of the relationship will be in the State of Florida, with Texas and Pennsylvania expected to follow.

**Competition**

*TULSA-PRO®*

The TULSA-PRO® system is intended to ablate benign and malignant prostate tissue, however there are other treatment options for prostate disease. There are currently no marketed devices indicated for the treatment of prostate diseases or prostate cancer and our FDA indication and CE mark in the EU also do not include treatment of any particular disease or condition. However, there are a number of devices indicated for the destruction or removal of prostate tissue and devices indicated for use in performing surgical procedures that physicians and surgeons currently utilize when treating patients with prostate disease, including prostate cancer. Approaches that physicians and surgeons currently use to address prostate disease include: (1) watchful waiting/active surveillance; (2) simple prostectomy; (3) radical prostatectomy (includes open, laparoscopic and robotic procedures); (4) radiation therapies including, external beam radiation therapy, brachytherapy and high dose radiation; (5) cryoablation; and (6) trans-rectal high intensity focused ultrasound ("**HIFU**"). In addition, certain adjunct or less common procedures are used or are under development to address prostate disease, such as androgen deprivation therapy and proton beam therapy.
Each of the foregoing competing options have their own limitations and benefits and may only be appropriate for limited patient populations. For example, active surveillance is generally recommended for patients who have been diagnosed with earlier stage, lower risk, disease where the possibility of side effects from intervention may outweigh the expected benefit of the chosen procedure. For clinicians and patients, the gap between active surveillance and the most commonly utilized options of surgery or radiation therapy imposes the possibility of substantial side effects, creating a need for a less invasive methodology to remove diseased prostate tissue that is both radiation and incision-free and provides a more favorable side-effect profile.

Profound believes that the flexibility of the TULSA-PRO® system may allow the Company to demonstrate its use as a tool for ablating benign and malignant diseased prostate tissue with greater speed and precision than current options while minimizing potential side effects. Profound believes that the TULSA-PRO® system may overcome certain limitations of other devices and methodologies for removing or addressing diseased prostate tissue including HIFU, such as complications associated with trans-rectal delivery and limitations relating to prostate size. Profound believes that a transurethral (inside out) ablation approach with millimeter accuracy has advantages over HIFU in ablating the whole gland safely.

In USD$ (000s)

*Sonalleve®*

The treatment choices for uterine fibroids usually depend on the symptoms of the patient, size of the fibroid, desire for future pregnancy and preference of the treating gynecologist. The most common treatment options for uterine fibroids include: (1) hormonal medications including gonadotrophin releasing hormone agonists; (2) progesterone releasing intra-uterine devices; (3) surgical procedures such as hysterectomy and myomectomy; and (4) uterine artery embolization.

Profound believes that the Sonalleve® system may provide a treatment option that is more convenient and comfortable with fewer side effects than hormonal medications or surgical procedures, such as hysterectomy or myomectomy.

**Reimbursement**

Profound's ability to successfully commercialize the Company's products depends in large part on the extent to which coverage and adequate reimbursement for such products and related treatments or procedures will be available from government health administration authorities, government and private health insurers, and other organizations or third-party payors. Pricing and reimbursement procedures and decisions vary from country to country. Many government health authorities and private payors condition payment on the cost-effectiveness of the product. Even if a device is FDA cleared or CE marked or has received other regulatory clearance or approval, there is no guarantee that third-party payors will reimburse providers or patients for the cost of the device and related procedures or that the amount of such reimbursement will be adequate to cover the cost of the device. The availability of coverage and adequate reimbursement to hospitals and clinicians using our products therefore is important to our ability to generate revenue and Profound plans to pursue coverage and reimbursement for the Company's products in the key markets where the Company has regulatory approvals. Successful commercialization of the Company's approved products will also depend on the cost of the system and the availability of coverage and adequate reimbursement from third-party payors.

Although Profound expects there to be an out-of-pocket market for the Company's approved products, an out-of-pocket market alone is unlikely to be sufficient to support successful commercialization of the Company's products. To date, the Company's products do not have significant coverage or reimbursement from government or third-party payers in the jurisdictions where they are approved. A C-Code is a unique temporary product code established by Centers for Medicare & Medicaid Services ("**CMS**") for the Hospital Outpatient Prospective Payment System ("**OPPS**") to promote the adoption of new medical technology that otherwise had no codes to facilitate payment. C-Codes are used on Medicare OPPS claims but may also be recognized on claims from other providers or by other payment systems.

## HIGHLIGHTS

- On January 5, 2022, Profound announced the appointment of Kenneth Knudson as Chief Commercial Officer of the Company.
- On January 18, 2022, Profound announced that the first patients have been treated in the Level 1 "CAPTAIN" trial.
- On March 1, 2022, Profound confirmed the TULSA-PRO® system's compatibility with GE's 3T MRI scanners (the "**GE Project**") and signed the first site agreement for a TULSA-PRO® system interfaced with a GE scanner.

## SELECTED FINANCIAL INFORMATION

The following selected financial information as at and for the three months ended March 31, 2022 and 2021, has been derived from the interim unaudited condensed consolidated financial statements and should be read in conjunction with those interim condensed consolidated financial statements and related notes.

| | For the three months ended March 31, 2022 | 2021 |
|---|---|---|
| | $ | $ |
| Revenue | 1,364 | 711 |
| Operating expenses | 7,728 | 6,824 |
| Finance costs | 892 | 900 |
| Net loss for the period | 8,184 | 7,472 |
| Basic and diluted loss per share | 0.40 | 0.37 |
| | | |
| Total assets | 80,274 | 99,769 |
| Total non-current liabilities | 1,954 | 2,361 |

Revenue has increased due to the increased recurring revenue from US sales, as new sites are enrolled and patient procedures increase.

Operating expenses increased for the three months ended March 31, 2022, compared to the three months ended March 31, 2021, because of increased personnel and travel costs associated with sales.

The Company reported total assets of $80,274 as at March 31, 2022, as compared to $99,769 as at March 31, 2021. The decrease in 2022 was a result of expenditures throughout the period ended March 31, 2022.

In USD$ (000s)

## RESULTS OF OPERATIONS

| | Three months ended March 31 | | | |
|---|---|---|---|---|
| | 2022 $ | 2021 $ | Change $ | % |
| Revenue | 1,364 | 711 | 653 | 92% |
| Cost of sales | 928 | 459 | 469 | 102% |
| **Gross profit** | 436 | 252 | 184 | 73% |
| | | | | |
| **Expenses** | | | | |
| Research and development | 3,180 | 3,105 | 75 | 2% |
| General and administrative | 2,346 | 2,132 | 214 | 10% |
| Selling and distribution | 2,202 | 1,587 | 615 | 39% |
| **Total operating expenses** | 7,728 | 6,824 | 904 | 13% |
| | | | | |
| Net finance (income)/costs | 892 | 900 | (8) | -1% |
| | | | | |
| **Loss before income taxes** | 8,184 | 7,472 | 712 | 10% |
| | | | | |
| Income taxes | 31 | 27 | 4 | 15% |
| | | | | |
| **Net loss attributed to shareholders for the period** | 8,215 | 7,499 | 716 | 10% |
| | | | | |
| **Other comprehensive loss (income)** | | | | |
| Item that may be reclassified to profit or loss | | | | |
| Foreign currency translation adjustment - net of tax | 2,293 | 985 | 1,308 | 133% |
| Net loss and comprehensive loss for the period | 10,508 | 8,484 | 2,024 | 24% |
| | | | | |
| **Loss per share** | | | | |
| Basic and diluted net loss per Common Share | 0.40 | 0.37 | 0.03 | 8% |

**Revenue**

Profound deploys a recurring revenue business model in the United States to market TULSA-PRO®, charging a one-time bundled payment per patient that includes the supply of its one-time-use device, use of the system as well as Company's Genius services that support each TULSA center with clinical and patient recruitment. The Sonalleve® product is marketed primarily outside North America in European and Asian countries deploying a capital model. Outside of North America, Profound generates most of its revenues from its system sales (both TULSA-PRO® and Sonalleve®) in Europe and Asia where the Company deploys a more traditional hybrid business model, charging for the system separately as capital and an additional per patient charge for the one-time-use devices and associated Genius services.

Sales of Sonalleve® systems are primarily one-time capital sales with limited recurring service revenue. For the historical financial periods presented herein, Profound has generated revenues primarily from sales of systems and one-time-use devices through its partnerships with Siemens and Philips in the EU and Asia. As the Company expands its commercialization efforts, it anticipates generating revenues through in-house sales and marketing efforts, as well as from collaborative partnerships. In August 2019, the Company received FDA clearance for the TULSA-PRO® system in the United States, and accordingly the Company anticipates generating future revenues in that market.

For the three months ended March 31, 2022, the Company recorded revenue totaling $1,364 with $340 from the one-time sale of capital equipment and $1,024 from recurring – non-capital revenue, which consists of the sale of one-time-use devices, lease of medical devices, procedures and services associated with extended warranties. For the three months ended March 31, 2021, the Company recorded revenue totaling $711 with $234 from the one-time sale of capital equipment and $477 from recurring – non-capital revenue. The increase in revenue for the three months ended March 31, 2022, was the result of higher recurring revenues from US procedures.

Revenue on a quarter over quarter basis is expected to fluctuate in the near term given the Company is maintaining a limited European commercial effort and remains focused primarily on the US market. The economic downturn and uncertainty caused by the COVID-19 pandemic and global measures undertaken to contain its spread have affected all of the Company's operations to some extent and, in particular, have caused volatility in demand for the TULSA-PRO® systems and the one-time-use devices related thereto. Profound continues to experience the effects of these measures as they continue to be significant in Asia. This has resulted in a reduction in anticipated sales and led to delays in the Company's expectations regarding the rate at which agreements for new TULSA-PRO® user sites will be entered into and when user sites will become operational for the initiation of patient treatments. Despite the COVID-19 pandemic, patient treatments are continuing and Profound continues to identify potential new TULSA-PRO® user sites. It continues to be very challenging to gauge the magnitude of the impact expected from the virus' outbreak on our future sales.

**Cost of sales**

Cost of sales include cost of finished goods, inventory provisions, warranty, freight and manufacturing overhead expenses.

For the three months ended March 31, 2022, the Company recorded a cost of sales of $928, related to the sale of medical devices, capital and non-capital, which reflects a 32% gross margin. For the three months ended March 31, 2021, the Company recorded a cost of sales of $459, related to the sale of medical devices, capital and non-capital, which reflects a 35% gross margin. The gross margin was lower in Q1 2022 due to the revenue product mix.

**Operating Expenses**

Operating expenses consist of three components: research and development ("**R&D**"), general and administrative ("**G&A**") and selling and distribution expenses. Historically, R&D expenses have exceeded selling and distribution expenses; however, in the future Profound expects selling and distribution expenses to increase as the Company commercializes the TULSA-PRO® system in the United States.

*R&D Expenses*

R&D expenses are comprised of costs incurred in performing R&D activities, including new product development, continuous product improvement, investment in clinical trials and related clinical manufacturing costs, materials and supplies, salaries and benefits, consulting fees, patent procurement costs, and occupancy costs related to R&D activity.

For the three months ended March 31, 2022, R&D expenses were higher by $75 compared to the three months ended March 31, 2021. Clinical trial costs, travel, salaries and benefits and other increased by $70, $143, $645 and $34, respectively. The increases were due to CAPTAIN trial enrolment, traveling for off-site MRI testing and site installation and additional headcount. Offsetting these amounts were a decrease to materials by $560 due to verification and validation testing and completion of GE Project and decrease in share based compensation of $231 due to employee departures. Depreciation expenses decreased by $21 due to assets being fully depreciated.

*G&A expenses*

G&A expenses are comprised of management costs, including salaries and benefits, various management and administrative support functions, insurance and other operating and occupancy costs.

G&A expenses for the three months ended March 31, 2022, increased by $214 compared to the three months ended March 31, 2021. Salaries and benefits, consulting fees, travel and software by $189, $93, $14 and $140, respectively, due to additional headcount, increased legal, recruitment and accounting fees, increased travel as restrictions continue to be lifted and new license costs for the enterprise resource planning ("**ERP**") and customer relationship management software. In addition, amortization expense increased by $23 due to the capitalization of ERP costs. Offsetting these amounts were a decrease to shared based compensation of $250 which was due to retirement of employees.

*Selling and distribution expenses*

Selling and distribution expenses are comprised of business development costs related to the market development activities and commercialization of the Company's systems, including salaries and benefits, marketing support functions, occupancy costs related to marketing activity and other miscellaneous marketing costs.

Selling and distribution expenses for the three months ended March 31, 2022, were higher by $615 compared to the three months ended March 31, 2021. Salaries and benefits, share based compensation, travel and other expenses increased by $374, $244, $66 and $35, respectively, due to increased salesforce hired in the US and China, options awarded to employees, travel to new and existing sites and an increase in membership and subscription fees. Offsetting this amount was a decrease to consulting fees of $104 due to the hiring of full time staff and lower recruitment fees.

### Finance costs

Net finance costs are primarily comprised of the following: (i) the change in the fair value of the derivative liability warrants; (ii) the lease liability interest expense; (iii) foreign exchange gain or loss; (iv) interest income; and (v) the interest income on trade and other receivables.

Net finance costs for the three months ended March 31, 2022, were lower by $8 compared to the three months ended March 31, 2021, primarily due to a higher foreign exchange loss. During the three months ended March 31, 2022, the Company recognized $1,031 of foreign exchange loss, $44 interest income on trade and other receivables and a $77 gain on the change in fair value of the derivative liability warrants. The Company recognized interest income of $34 and lease liability interest expense of $16.

### Net loss

Net loss for the three months ended March 31, 2022, was $8,215 or $0.40 per Common Share, compared to a net loss of $7,499 or $0.37 per Common Share for the three months ended March 31, 2021. The increase in net loss was primarily attributed to an increase in R&D expense of $75, an increase in G&A expenses of $214 and an increase in selling and distribution expenses of $615. This was offset by an increase in gross profit of $184 and a decrease in net finance costs of $8.

## SUMMARY OF QUARTERLY FINANCIAL RESULTS

The summary financial information provided below is derived from the Company's interim financial statements for each of the last eight quarters that are prepared under IFRS in US dollars.

In USD$ (000s)

| | 2022 | | 2021 | | | 2020 | | |
|---|---|---|---|---|---|---|---|---|
| | Q1 | Q4 | Q3 | Q2 | Q1 | Q4 | Q3 | Q2 |
| | $ | $ | $ | $ | $ | $ | $ | $ |
| **Revenue** | 1,364 | 998 | 2,537 | 2,627 | 711 | 2,880 | 2,238 | 1,026 |
| **Cost of sales** | 928 | 501 | 1,550 | 1,411 | 459 | 1,737 | 765 | 610 |
| **Gross profit** | 436 | 497 | 987 | 1,216 | 252 | 1,143 | 1,473 | 416 |
| | | | | | | | | |
| **Operating expenses** | 7,728 | 10,225 | 8,594 | 7,600 | 6,824 | 6,051 | 6,615 | 4,356 |
| **Net finance costs** | 892 | 464 | (1,663) | 602 | 900 | 2,987 | 784 | 1,224 |
| **Loss before income taxes** | 8,184 | 10,192 | 5,944 | 6,986 | 7,472 | 7,895 | 5,926 | 5,164 |
| | | | | | | | | |
| **Income taxes** | 31 | (31) | 52 | 57 | 27 | (368) | 183 | 139 |
| | | | | | | | | |
| **Net loss for the period** | 8,215 | 10,161 | 5,996 | 7,043 | 7,499 | 7,527 | 6,109 | 5,303 |
| | | | | | | | | |
| **Loss per Common Share** | | | | | | | | |
| **Basic and diluted** | 0.40 | 0.49 | 0.29 | 0.35 | 0.37 | 0.38 | 0.33 | 0.33 |

The second quarter of 2020 experienced a partial reversal of the Q1 2020 foreign exchange gains resulting in higher net finance costs. Net loss for the period was higher due to these losses.

The third quarter of 2020 operating expenses increased because of the personnel hired, share based compensation awards and increased spending on R&D projects coupled with technology improvements.

The fourth quarter of 2020 was impacted by the decrease in the foreign exchange currency rate, triggering an unrealized foreign exchange loss. Net loss for the period was higher due to these losses.

The first quarter of 2021 was impacted by lower sales and higher operating costs. These changes were mainly attributed to the impact of COVID-19 and an increase in R&D projects.

The second quarter of 2021 operating expenses were higher due to increased headcount, material expenditures and stock-based compensation.

The third quarter of 2021 operating expenses were higher this quarter verses prior due to increased headcount, increased travel due to travel restrictions being removed and increased share-based compensation. In addition, there was also a decrease in finance costs due to the US dollar and Euro foreign currency rate, triggering an unrealized foreign exchange gain.

The fourth quarter of 2021 revenue was lower compared to prior quarters due to decreased one-time capital sales. Operating expenses were higher due to the increase in headcount and increased share-based compensation. In addition, there were minimal financing costs due to the US dollar and Euro foreign currency rate, triggering an unrealized foreign exchange loss offset by gain on the fair value of the derivative financial instrument.

The first quarter of 2022 revenue increased compared to the prior quarter as a result of the rise of recurring revenue from US procedures. Operating expenses remained relatively steady with a slight increase from additional headcount.

## LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2022, the Company had cash of $60,124 compared to $67,152 at December 31, 2021.

### Cash Flow

The Company manages liquidity risk by monitoring actual and projected cash flows. A cash flow forecast is performed regularly to ensure that the Company has sufficient cash to meet operational needs while maintaining sufficient liquidity.

In USD$ (000s)

The Company may require additional capital to fund R&D activities and any significant expansion of operations. Potential sources of capital could include equity and/or debt financings, development agreements or marketing agreements, the collection of revenue resulting from future commercialization activities and/or new strategic partnership agreements to fund some or all costs of development. There can be no assurance that the Company will be able to obtain the capital sufficient to meet any or all of the Company's needs. The availability of equity or debt financing will be affected by, among other things, the results of R&D, the Company's ability to obtain regulatory approvals, the market acceptance of the Company's products, the state of the capital markets generally, strategic alliance agreements and other relevant commercial considerations. In addition, if the Company raises additional funds by issuing equity securities, existing security holders will likely experience dilution, and any incurring of indebtedness would result in increased debt service obligations and could require the Company to agree to operating and financial covenants that would restrict operations. Any failure on the Company's part to raise additional funds on terms favourable to the Company or at all may require the Company to significantly change or curtail current or planned operations in order to conserve cash until such time, if ever, that sufficient proceeds from operations are generated, and could result in the Company not being in a position to take advantage of business opportunities, in the termination or delay of clinical trials for our products, in curtailment of product development programs designed to identify new products, in the sale or assignment of rights to technologies, product and/or an inability to file market approval applications at all or in time to competitively market products.

| | Three months ended March 31, | |
|---|---|---|
| | **2022 $** | **2021 $** |
| | | |
| Cash provided by (used in) operating activities | (7,859) | (6,271) |
| Cash provided by (used in) investing activities | - | (181) |
| Cash provided by (used in) financing activities | (75) | 1,201 |
| Foreign exchange on cash | 906 | (149) |
| **Net increase (decrease) in cash** | (7,028) | (5,400) |

*Operating Activities*

Net cash provided by (used in) operating activities for the three months ended March 31, 2022, was $(7,859) versus $(6,271) for the three months ended March 31, 2021. The principal use of the operating cash flows during this three month period related to increased employee headcount and increased travel expenditures.

*Investing Activities*

Net cash provided by (used in) investing activities for the three months ended March 31, 2022, were $nil versus $(181) for the three months ended March 31, 2021. The cash flows from 2021 related to ERP implementation costs.

*Financing Activities*

Net cash provided by (used in) financing activities for the three months ended March 31, 2022, were $(75) versus $1,201 for the three months ended March 31, 2021. These cash flows in 2021 related to the exercise of options and warrants.

*Foreign Exchange on Cash*

Cash was impacted by the change in the foreign exchange rates for our foreign currency denominated cash. The value of our currencies increased, resulting in an increase in the Company's cash holdings.

The Company's cash requirements depend on numerous factors, including market acceptance of the Company's products, the resources devoted to developing and supporting the products and other factors. Profound expects to continue to devote substantial resources to expand procedure adoption and acceptance of the Company's products.

In USD$ (000s)

**Contractual obligations**

The following table summarizes the Company's significant contractual obligations:

| | March 31, 2022 | | | |
|---|---|---|---|---|
| | **Carrying amount $** | **Future cash flows $** | **Less than 1 Year $** | **Between 1 year and 5 years $** |
| Accounts payables and accrued liabilities | 2,778 | 2,778 | 2,778 | - |
| Lease liability[1] | 1,336 | 1,510 | 316 | 1,194 |
| **Total** | 4,114 | 4,288 | 3,094 | 1,194 |

[1] Present value of the lease payments that are not paid, discounted using the interest rate implicit in the lease.

**Non-IFRS Financial Measures**

Non-IFRS measures are not recognized measures under IFRS and do not have a standardized meaning prescribed by IFRS. These measures are defined with reference to the nearest comparable IFRS measure such that a reconciliation to the nearest comparable IFRS measure can be completed. Accordingly, these measures may not be comparable to similar measures presented by other companies. Profound uses non-IFRS measures in order to provide additional financial information to complement the closest IFRS measures in order to provide investors with a further understanding of the Company's operations from management's perspective. Investors should not consider that these non-IFRS measures are a substitute for analyses of the financial information that Profound reports under IFRS. Profound uses these non-IFRS measures in order to provide investors with a supplemental measure of our operating performance and thus highlight trends in our business that may not otherwise be apparent when relying solely on IFRS measures.

The Company's working capital (defined as current assets less current liabilities) is a non-IFRS financial measure. Working capital is used to fund operations and meet short-term obligations. If the Company has enough working capital, it can continue to pay its employees and suppliers and meet other obligations, such as interest payments and taxes, even if it runs into cash flow challenges. The working capital as at March 31, 2022, as compared to the Company's working capital as at December 31, 2021 is set forth in the table below.

| | **March 31, 2022 $** | **December 31, 2021 $** |
|---|---|---|
| Current assets | 70,651 | 77,125 |
| Less: Current liabilities | 3,856 | 4,155 |
| **Working capital** | 66,795 | 72,970 |

Working capital has decreased by $6,175 with a surplus of $66,795 at March 31, 2022, compared to the surplus of $72,970 at December 31, 2021. The change in working capital is due to a decrease in current assets of $6,474, which was primarily the result of the decreased cash balance of $7,028. Current liabilities decreased by $299 due to the timing of accruals and payments.

## COMMITMENTS & CONTINGENCIES

All directors and officers of the Company are indemnified by the Company for various items including, but not limited to, all costs to settle lawsuits or actions due to their association with the Company, subject to certain restrictions. The Company has purchased directors' and officers' liability insurance to mitigate the cost of any potential future lawsuits or actions. The term of the indemnification is not explicitly defined but is limited to events for the period during which the indemnified party served as a director or officer of the Company. The maximum amount of any potential future payment cannot be reasonably estimated but could have a material adverse effect on the Company.

The Company has also indemnified certain lenders and underwriters in relation to certain debt and equity offerings and their respective affiliates and directors, officers, employees, shareholders, partners, advisers and agents and each other person, if any, controlling any of the underwriters or lenders or their affiliates against certain liabilities.

In USD$ (000s)

## FINANCIAL INSTRUMENTS

The Company's financial instruments consist of cash, trade and other receivables, accounts payable and accrued liabilities, lease liabilities and other liabilities. The fair values of these financial instruments and other liabilities, approximate carrying value because of their short-term nature. For the non-current trade and other receivables, the fair value is also not significantly different from the carrying amount. Financial assets measured at amortized cost include cash and trade and other receivables.

The fair value of the Company's derivative financial instruments is based on the valuation techniques described and is considered level 2 in the fair value hierarchy.

Financial liabilities measured at amortized cost include accounts payable and accrued liabilities, lease liabilities and other liabilities.

The Company's financial instruments are exposed to certain financial risks including credit risk, liquidity risk, currency risk and interest rate risk. There have been no significant changes to those risks impacting the Company since December 31, 2021, nor has there been a significant change in the composition of its financial instruments since December 31, 2021.

## RELATED PARTY TRANSACTIONS

Key management includes the Company's directors and senior management team. Additional information on the senior management team can be found in the Company's AIF. The remuneration of directors and the senior management team were as follows:

| | Three months ended | |
|---|---|---|
| | **2022 $** | **2021 $** |
| Salaries and employee benefits | 759 | 821 |
| Directors' fees | 63 | 55 |
| Share-based compensation | 156 | 542 |
| **Total** | 978 | 1,418 |

Executive employment agreements allow for additional payments in the event of a liquidity event, or if the executive is terminated without cause.

## OUTSTANDING SHARES

As at May 9, 2022, the date of this MD&A, the Company had the following securities outstanding:

| | Number |
|---|---|
| Common Shares | 20,779,517 |
| Share purchase options | 1,885,962 |
| Warrants | 724,983 |
| RSUs | 206,983 |

## OFF-BALANCE SHEET ARRANGEMENTS

The Company has no off-balance sheet arrangements.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of consolidated financial statements in conformity with IFRS requires management to make estimates and judgements that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the period. Actual results could differ from these estimates. As additional information becomes available or actual amounts are determinable, the recorded estimates are revised and reflected in operating results in the period in which they are determined.

**Critical accounting policies**

*Revenue*

To determine revenue recognition for arrangements the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The Company derives its revenues primarily from the lease and sale of medical devices and the sale of certain one-time-use devices. Capital equipment consists of one-time revenue for the sale of capital equipment including installation fees. Recurring – non-capital revenue consists of the sale of one-time-use devices, lease of medical devices, procedures and services associated with extended warranties. Revenue is recognized when a contractual promise to a customer (performance obligation) has been fulfilled by transferring control over the promised goods or services, generally at the point in time of shipment to or receipt of the products by the customer or when the services are performed. When contracts contain customer acceptance provisions, revenue is recognized on the satisfaction of the specific acceptance criteria.

The amount of revenue to be recognized is based on the consideration the Company expects to receive in exchange for its goods and services. For contracts that contain multiple performance obligations, the Company allocates the consideration to which it expects to be entitled to each performance obligation based on relative standalone selling prices and recognizes the related revenue when or as control of each individual performance obligation is transferred to customers.

Service revenue related to installation and training is recognized over the period in which the services are performed. Service revenue related to extended warranty service is deferred and recognized on a straight-line basis over the extended warranty period covered by the respective customer contract.

**Critical accounting estimates**

*Impairment of non-financial assets*

The Company reviews amortized non-financial assets for impairment whenever events or changes in circumstances indicate the carrying amount of the assets may be impaired. It also reviews goodwill annually for impairment. If the recoverable amount of the respective non-financial asset is less than its carrying amount, it is considered to be impaired. In the process of measuring the recoverable amount, management makes assumptions about future events and circumstances. The actual results may vary and may cause significant adjustments.

*Trade and other receivables*

The key judgments and estimates used in determining the amortized cost for trade and other receivables are the estimated collection period and the discount rate applied to the cash flow projections.

## DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROLS OVER FINANCIAL REPORTING

Disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure.

The Chief Executive Officer and the Chief Financial Officer of the Company (collectively the "**Certifying Officers**") are responsible for establishing and maintaining disclosure controls and procedures ("**DC&P**") and internal control over financial reporting ("**ICFR**"), as those

terms are defined in *National Instrument 52-109 Certification of Disclosure in Issuer's Annual and Interim Filings*, and in applicable SEC rules and regulations, for the Company.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. These inherent limitations include, but are not limited to, human error and circumvention of controls and as such, there can be no assurance that the controls will prevent or detect all misstatements due to errors or fraud, if any.

Management concluded that internal control over financial reporting was not effective as of March 31, 2022 as a result of a material weakness in internal control over financial reporting from a prior period. See "*Control Environment*" and "*Status of Remediation Plan*" below for a description of the foregoing material weakness and the Company's evaluation and remedial activities taken in respect of such.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the assessment of the effectiveness of our internal control over financial reporting, management identified a material weakness that existed as of March 31, 2022 in the control environment.

**Control Environment**

The Company did not design or implement adequate oversight processes and structures, or an organizational design to support the achievement of the Company's objectives in relation to internal controls. The Company identified a deficiency in internal controls, primarily due to the control environment not supporting the increasing complexity of the share based compensation arrangements for employees and directors and review of third-party calculations. As a result, an issue existed within the control environment that impacted the ability of the Company to maintain effective internal control over financial reporting. This material weakness contributed to the following:

- The Company did not design and maintain effective controls over the review of inputs utilized in the calculation of the share based compensation expense. Specifically, the Company did not design appropriate controls over the valuation and review of third party calculations.

While there was a material weakness, no restatement for any previous periods were required as the impact was immaterial in the aggregate and did not have a pervasive impact on ICFR.

**Status of Remediation Plan**

Management, with the assistance of external consultants, are reviewing and revising our internal control over financial reporting. Management is committed to implementing changes to our internal control over financial reporting to ensure that the control deficiencies that contributed to the material weaknesses are remediated. The following remedial activities are in process:

- We have increased the number of finance and accounting personnel and have redesigned financial reporting structures within the organization to establish clear responsibility and accountability for key financial reporting processes and controls. We have hired additional financial reporting personnel with an appropriate level of internal controls and accounting knowledge, training and experience commensurate with our financial reporting requirements, and are actively working to identify additional resources.

- We are continuing to establish an internal audit function and we are engaging external consultants to assist management with designing and implementing internal controls. As a result, a project was commenced to reassess risks related to financial reporting, understand and document significant financial reporting processes, and to re-assess the design and operation of key controls. This project is expected to continue until management has determined that deficiencies have been remediated and our internal control over financial reporting are operating effectively.

Management believes these actions will remediate the material weaknesses and have not completed all the corrective processes, procedures and related evaluation or remediation that we believe are necessary. There were no share based compensation transactions present in Q1 2022 to apply our remediation plan against. As soon as we complete a transaction, we will implement our new procedures. As we continue to evaluate and work to remediate the material weaknesses, we may need to take additional measures to address the control deficiencies. Until the remediation steps set forth above, including the efforts to implement any additional control activities identified through our remediation processes, are fully implemented and concluded to be operating effectively, the material weaknesses described above will not be considered fully remediated.

Other than disclosed above, there have been no significant changes to the Company's ICFR for the three months ended March 31, 2022, which have materially affected, or are reasonably likely to materially affect the Company's ICFR.

## RISK FACTORS

For a detailed description of risk factors associated with the Company, refer to the "Risk Factors" section of the AIF, which is available on SEDAR at www.sedar.com and filed as an exhibit to the 40-F, available on EDGAR at www.sec.gov.

In addition, the Company is exposed to a variety of financial risks in the normal course of operations, including risks relating to cash flows from operations, liquidity, capital reserves, market rate fluctuations and internal controls over financial reporting. Our overall risk management program and business practices seek to minimize any potential adverse effects on our consolidated financial performance. Financial risk management is carried out under practices approved by our audit committee. This includes reviewing and making recommendations to the board of directors regarding the adequacy of our risk management policies and procedures with regard to identification of the Company's principal risks, and implementation of appropriate systems and controls to manage these risks.

## ADDITIONAL INFORMATION

Additional information relating to the Company, including the AIF the other exhibits to the 40-F, is available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov. The Common Shares are listed for trading on the TSX under the symbol "PRN" and on Nasdaq under the symbol "PROF".